Docket No.: TIP-0056USPCT EFS Filing-

## **AMENDMENTS TO CLAIMS**

## **Listing of Claims**

1. (Currently Amended) A process for preparing compound of formula (6),

addition salts, polymorphic and/or pseudopolymorphic forms thereof; <del>characterized in that said process comprises</del> comprising:

(i) introducing an isobutylamino group in compound of formula (1)

wherein

**PG** represents an amino-protecting group;

 $\mathbf{R_1}$  is hydrogen or  $\mathbf{C}_{1\text{-}6}$ alkyl;

- (ii) introducing a p-nitrophenylsulfonyl group in the resultant compound of step (i);
- (iii) reducing the nitro moiety of the resultant compound of step (ii);
- (iv) deprotecting the resultant compound of step (iii); and
- (v) coupling the resultant compound of step (iv) with a (3R,3aS,6aR)-hexahydrofuro [2,3-b] furan-3-yl derivate.
- 2. (Currently Amended) A process according to claim 1 for preparing compound of formula (6), <u>comprising characterized in that said process comprises</u> the steps of: introducing an isobutylamino group in compound of formula (1');

$$\begin{array}{c|c} & & & \\ & & \\ & & & \\ & & & \\ & & & \\ & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ &$$

to obtain compound of formula (2');

introducing a p-nitrophenylsulfonyl group into compound of formula (2') to obtain compound of formula (3');

reducing the nitro moiety of compound of formula (3') to obtain compound of formula (4');

$$\begin{array}{c|c} & & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ & & & \\ &$$

deprotecting compound of formula (4') to obtain compound of formula (5)

Docket No.: TIP-0056USPCT EFS Filing-

coupling compound of formula (5) with (3R,3aS,6aR)-hexahydrofuro [2,3-b] furan-3-yl derivate to obtain compound of formula (6).

- 3. (Currently Amended) A process according to <u>claim 1</u> any one of claims 1 to 2 wherein step (i) is carried out in toluene.
- 4. (Currently Amended) A process according to <u>claim 1 any one of claims 1 to 3</u> wherein step (ii) is carried out in toluene, ethylacetate, methylene chloride, dichloromethane, or tetrahydrofuran.
- 5. (Currently Amended) A process according to <u>claim 1</u> any one of claims 1 to 4 wherein step (iii) is carried out in the presence of up to 10 mol % primary or secondary amine, preferably ethanolamine, with palladium on charcoal under a hydrogen atmosphere.
- 6. (Currently Amended) A process according to <u>claim 1 any one of claims 1 to 5</u> wherein step (iv) is carried out in acidic or basic conditions.
- 7. (Currently Amended) A process according to <u>claim 2any one of claims 1 to 6</u> wherein compound of formula (5) is crystallized by dissolving in a solvent system, adjusting the pH to a value higher than 9 and keeping the concentration of compound of formula (5) in solution in a value between 4% and 15% (w/w).
- 8. (Currently Amended) A process according to <u>claim 2</u><del>any one of claims 1 to 7</del> wherein compound of formula (5) is crystallized at a temperature between 0°C and 10°C.
- 9. (Currently Amended) A process according to <u>claim 7 any one of claims 7 to 8</u> wherein seed crystals of compound of formula (5) are added during crystallization.

Docket No.: TIP-0056USPCT EFS Filing-

10. (Currently Amended) A process according to <u>claim 7</u> any one of claims 7 to 9 wherein the solvent system comprises one or more water-miscible solvents and water.

- 11. (Currently Amended) A process according to <u>claim 7</u> any one of claims 7 to 9 wherein the solvent system comprises one or more water-immiscible solvents and water.
- 12. (Original) A process according to claim 10 wherein the solvent system is methanol, isopropanol, and water in a ratio 1:6.5:8 respectively.
- 13. (Currently Amended) A process according to <u>claim 2any one of claims 1 to 12</u> wherein (3R,3aS,6aR)-hexahydrofuro [2,3-b] furan-3-ol or a precursor thereof is reacted with bis-(4-nitrophenyl)carbonate before coupling to compound of formula (5).
- 14. (Currently Amended) A process according to <u>claim 2any one of claims 1 to 12</u> wherein (3R,3aS,6aR)-hexahydrofuro [2,3-b] furan-3-ol or a precursor thereof is reacted with disuccinimidyl carbonate before coupling to compound of formula (5).
- 15. (Currently Amended) A process according to claim 13 or 14-wherein the reaction of (3R,3aS,6aR)-hexahydrofuro [2,3-b] furan-3-ol or a precursor thereof and the carbonic acid derivative is activated by an (amine-) base, preferably triethylamine or pyridine.
- 16. (Original) Use of compound of formula (5), addition salts, polymorphic and/or pseudopolymorphic forms thereof for the preparation of compound of formula (6).
- 17. (Original) Use of compound of formula (5) according to claim 16, wherein compound of formula (5) is in the form of a free base.
- 18. (Currently Amended) Use of a compound according to <u>claim 1</u> any one of claims 1 to 17 as an intermediate for preparing compound of formula (6).
- 19. (New) A process according to claim 2 wherein step (i) is carried out in toluene.